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| EXAMINER |
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ADAMS, AMANDA S

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| ART UNIT | PAPER NUMBER |
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3731

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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/768,994

Applicant(s)

CHRISTOPHERSON, MARK A.

Examiner

Amanda Adams

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,22-24,31-49 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,22-24,31-49 and 51 is/are rejected.
- 7) ☒ Claim(s) 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 1-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group I drawn to a system, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 28, 2006.

Claim Objections

2. Claim 43 is objected to because of the following informalities: In line 4, "prostrate" is misspelled, and the correct spelling is "prostate". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 43-45, 47-49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al (US 6,353,751).
5. Regarding claim 43, Swanson discloses the invention substantially as claimed including:

- a. Ablation means for delivering ablation energy to a first target tissue site within a prostate of a patient,
 - b. Means for deploying and retracting the ablation means within the prostate,
 - c. Means for sensing a position of the means for deploying and retracting the ablation means,
 - d. And means for activating an advisory after delivery of the ablation energy until the sensed position indicates that the means for deploying and retracting the ablation means has fully retracted the ablation means (col. 7, lines 2-30).
6. Regarding claim 51, Swanson discloses means for repositioning the ablation means within the prostate such that the ablation means is aligned with a second target tissue site within the prostate, and wherein the ablation means delivers the ablation energy to the second target tissue site (col. 6, lines 35-40 and col. 7, lines 2-18).
7. Regarding claim 44, Swanson discloses that the needle position indicator confirms when the ablation needle is fully retracted within the catheter, that the needle position indicator presents whether the ablation needle is fully deployed from the catheter, and that the needle position indicator presents the extent to which the ablation needle is deployed from the catheter (col. 7, lines 1-20, this system is capable of this limitation).
8. Regarding claims 45 and 48, Swanson discloses the position indicator comprises at least one of lights, colored lights, flashing lights, audible tones, alarms, graphical images and text messages (col. 16, line 34; audible and visual indicators).

9. Regarding claim 47, Swanson discloses the position indicator comprises an audible tone (col. 16, line 34).
10. Regarding claim 49, Swanson discloses means for continuously presenting the sensed position of the ablation needle during an ablation procedure (col. 7, lines 2-18; the system is capable of continuous sensing).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US 6,353,751) in view of Lundquist et al (US 5,549,644).
13. Swanson discloses the invention substantially as claimed but fails to disclose that the means for confirming comprises means for deactivating the advisory. However, Lundquist teaches that the means for confirming when the ablation needle is fully retracted comprises means for deactivating the advisory (col. 26, lines 38-46). This allowsthe advisory to be turned off once the surgeon realizes that the device has been fully retracted, so that the surgeon will be able to notice any additional changes in position; i.e. if the advisory was continuous the surgeon may incorrectly think that the ablative needle is fully retracted. Therefore it would have been obvious to include a means for deactivating the advisory.

14. Claims 17, 22-24, 31-35, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US 6,353,751) in view of Smith et al (US 5,431,645).

15. Regarding claim 17, Swanson discloses the invention substantially as claimed including:

- e. A transurethral catheter (fig. 2 [19]),
- f. An ablation needle extendable from the catheter by an actuator to penetrate a prostate of a patient ([21]),
- g. An ablation energy generator to deliver ablation energy to the prostate via the ablation needle ([20]),
- h. And a needle position indicator operably positioned relative to the actuator, the needle position indicator further comprising an actuation position sensor that senses the position of the actuator (col. 7, lines 13-20; see a further explanation ins the section Response to Aguments).

16. Swanson fails to disclose a variable resistive element. However, Smith teaches a variable resistive element to determine the extent to which the needle is extended in view of the position of the actuator (col. 14, lines 57-67). This is an old and well-known way of sensing the position of one element in relation to the position of another element. Further, due to lack of criticality in the specification, the variable resistive element was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conductive contact. Therefore, it would have been obvious to use a variable resistive element because it is capable of working equally as

well as the conductive contact disclosed by Swanson. The feedback provided by the variable resistive element can also be converted into an audible or visual signal.

17. Regarding claims 22-24, Swanson further discloses that the needle position indicator confirms when the ablation needle is fully retracted within the catheter, that the needle position indicator presents whether the ablation needle is fully deployed from the catheter, and that the needle position indicator presents the extent to which the ablation needle is deployed from the catheter (col. 7, lines 1-20, this system is capable of this limitation).

18. Regarding claim 31, Swanson further discloses that the position indicator comprises an audible tone (col. 16, line 34).

19. Regarding claim 32, Swanson further discloses the audible tone comprises an advisory activated when the needle is to be repositioned within the prostrate if the position of the ablation needle is not fully retracted within the catheter (col. 16, lines 30-37 and col. 7, lines 1-20).

20. Regarding claim 33, Swanson further discloses a controller to determine a time to reposition the ablation needle within the prostrate (col. 16, lines 20-37).

21. Regarding claim 34, Swanson further discloses the controller is connected to receive a needle position signal from the needle position sensor, and wherein the controller activates the advisory at the determined time if the needle position signal does not correspond to a needle that is fully retracted within the catheter (col. 16, lines 20-37).

22. Regarding claim 35, Swanson further discloses the controller generates the advisory until the needle position signal corresponds to a needle that is fully retracted within the catheter (col. 16, lines 20-37).

23. Regarding claim 37, Swanson further discloses that the position indicator can comprise either flashing lights or audible tones (col. 16, line 34).

24. Regarding claims 38 and 39, Swanson discloses the invention substantially as claimed but fails to disclose the position indicator located on a handle through which a user controls the position of the ablation needle and the application of ablation energy, or the position indicator located on the ablation energy generator. However, due to lack of criticality in the specification, placing the position indicator in the handle or on the ablation energy generator was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a position indicator in any other visible location. Therefore, it would have been obvious to place the position indicator on either the handle or the ablation energy generator because there it would be capable of working equally as well as placing a position indicator on any other visible location, such as a display monitor.

25. Regarding claims 40 and 41, Swanson discloses the invention substantially as claimed above but fail to disclose that the position indicator includes at least one of a graphical image and a text message presented on a user interface indicating the extent to which the ablation needle is deployed or retracted. However, due to lack of criticality in the specification, having a position indicator that is a graphical image or a text message was shown to solve no particular problem, serve no particular purpose and

provide no additional benefit as opposed to an audible position indicator. Therefore, it would have been obvious to have a graphical or textual position indicator because those are capable of alerting a surgeon equally as well as an audible position indicator.

26. Regarding claim 42, Swanson discloses a position sensor to continuously sense the position of the needle within the catheter, and wherein the position indicator continuously presents the sensed position of the needle (col. 7, lines 2-18).

27. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US 6,353,751) in view of Smith et al (US 5,431,645), and further in view of Lundquist et al (US 5,549,644).

28. Swanson in view of Smith discloses the invention substantially as claimed, but fail to disclose the following which is taught by Lundquist:

29. Regarding claim 36, Lundquist teaches that a determined time to reposition an ablation needle within a prostrate is after delivery of the ablation energy (col. 26, lines 38-46). This allows ablation energy to be delivered to one specific area, and then for the device to be moved without causing harm to healthy tissue, and then for it to ablate another area of tissue. Therefore it would have been obvious to wait to reposition the device until after the ablation energy have been delivered at the first location.

Response to Arguments

30. The amendments with respect to claim 51 have been considered and the previous objection to claim 51 has been withdrawn.

31. Applicant's arguments with respect to claims 17 and its depending claims have been considered but are moot in view of the new ground(s) of rejection. Smith et al teaches the limitation of amended claim 17 that are not disclosed by Swanson et al, as explained earlier in this office action.

32. Applicant's arguments filed 2/5/07, with respect to claim 43 and its depending claims have been fully considered but they are not persuasive. Swanson can still be used as prior art to reject the claim because no structure for the menas has been given in claim 43. Therefore the structure of Swanson, which is capable of all of the functions described in claim 43, is still prior art that meets all of the limitations of the amended claim.

33. Applicable to both claims 17 and 43, the last three lines of page 8 in the remarks filed on 2/5/2007 refers to the applicant's specification, paragraph 32. Here it is pointed out that " 'the position of the actuator 20 corresponds to the position of the needle 19' and therefore the position of the needle can be inferred from the position of the actuator". This is being interpreted by the examiner to mean that any sensor that can sense the position of the needle also, by default, senses the position of the actuator. Therefore the rejections of claims 17 and 43 are maintained, as this limitation is anticipated by Swanson et al.

Conclusion

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

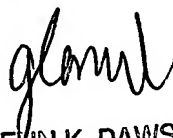
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA

ASA 4/27/07


GLENN K. DAWSON
PRIMARY EXAMINER